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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/963,096	11/03/1997	ZUO-YU ZHAO	190.0001-010	9667
27310	7590	04/08/2004	EXAMINER	
PIONEER HI-BRED INTERNATIONAL INC. 7100 N.W. 62ND AVENUE P.O. BOX 1000 JOHNSTON, IA 50131			FOX, DAVID T	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 04/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 08/963,096	<b>Applicant(s)</b> ZHAO ET AL.	
	<b>Examiner</b> David T. Fox	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 90-97 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 90-97 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The amendment and accompanying arguments of 12 November 2003 have obviated the product of nature rejection under 35 USC 101, and the outstanding obviousness rejections under 35 USC 103.

The application should be reviewed for errors. Errors appear, for example, in claims 94 and 97 which recite "PHPN46". However, the specification recites --PHN46--, and U.S. Patent 5,567,861 to Niebur teaches maize inbred line PHN46. There is no teaching in the instant specification or the prior art of inbred maize plant PHPN46.

Claims 94 and 97 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite in their failure to employ proper Markush terminology. See MPEP 2173.05(h). Amendment of line 2 of each claim to replace "a group" with ---the group---, and to insert ---selected--- before "from", would obviate this rejection.

The amendment of 26 March 1999 remains objected to for its inclusion of NEW MATTER regarding the replacement of "PHP28" with ---PHP38---, as stated on page 2 of the last Office action.

Applicant's arguments filed 12 November 2003 have been fully considered but they are not persuasive. Applicant urges that "PHP28" was merely a typographical error. However, there is no evidence to support this assertion. The three non-A188 inbreds utilized in the specification to produce hybrids were PHJ90, PHN48 and "PHPP8" (see,

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e.g., page 40 of the specification. The three non-A188 inbreds utilized in the specification for direct transformation were PHJ90, PHN48 and "PHP28" (see, e.g., page 25 of the specification, line 23 and page 42 of the specification, lines 13 and 22). There is no recitation of "PHP38" anywhere in the specification or originally filed claims.

Claims 94 and 97 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As discussed above and previously, there is no basis in the specification for the term "PHP38". Accordingly, claims reciting this term are drawn to NEW MATTER.

Claims 90-93 and 95-96 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to Agrobacterium-mediated transformed maize inbreds PHJ90, PHN46 and PHP28(38) prepared by the disclosed method, does not reasonably provide enablement for claims broadly drawn to any Agrobacterium-mediated transformed maize inbred which is not A188. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated in the last Office action on pages 2-6 for claims 90-91.

Applicant's arguments filed 12 November 2003 have been fully considered but they are not persuasive. Applicant urges that the scope of enablement rejection is

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improper, given the patenting of each of the exemplified non-A188 inbred lines as claimed in claims 94 and 97, and given the assertion that the three inbreds belong to three different heterotic groups.

The Examiner maintains that the specification does not in fact teach anything about maize inbred PHP38 regarding its parentage or genetic makeup. Instead, the specification teaches PHP28, whose parentage and genetic makeup is unclear. Regarding the remaining exemplified non-A188 inbreds, Applicant is invited to elucidate the non-relatedness of these inbreds by elaborating on their parentage and other characteristics. Applicant is also invited to support his assertion that the three inbreds belong to different heterotic groups, and to explain why an assignment to different heterotic groups is an indication of genetic diversity. These explanations should be in the form of a declaration under 37 CFR 1.132. In the absence of such information, the genetic relatedness or unrelatedness of PHP28, PHN46 and PHJ90 is unclear, so that it is unclear whether these species constitute a truly representative genus of the broadly claimed genus in claim 90, which encompasses any non-A188 maize inbred line of any genetic makeup.

Claims 90-93 and 95-96 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldman et al (U.S. 5,177,010), as stated on page 7 of the last Office action for claims 90-91.

Claims 90-93 and 95-96 are rejected under 35 U.S.C. 102(e) as being anticipated by Goldman et al (U.S. 6,020,539), as stated on page 7 of the last Office action for claims 90-91.

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Applicant's arguments filed 12 November 2003 have been fully considered but they are not persuasive. Applicant urges that the amendment of the claims to recite a process for making the claimed maize plants, wherein said process involves the direct inoculation of intact immature maize embryos, obviates the rejections over the Goldman et al patents.

The Examiner maintains that the particular explant used for inoculation with Agrobacterium, in order to make the claimed Agrobacterium-transformed maize plants (which would inherently contain at least one 25 base-pair T-DNA border sequence), would not confer a patentable distinction to the resultant Agrobacterium-transformed maize plant.

See In re Best, 195 USPQ 430, 433 (CCPA 1977), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

See In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

Claims 92 and 95 are rejected under 35 U.S.C. 102(a) as being anticipated by Ishida et al.

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Claims 92 and 95 are drawn to transformed maize cells and plants of any genotype, which are produced by culturing immature embryos with *Agrobacterium* on particular media containing particular mineral salts.

Ishida et al teach transformed A188 plants produced by culturing immature maize embryos with *Agrobacterium* on L6 salts-containing medium. Thus, Ishida et al anticipate claim 95 which recites "non-MS salts". Given the failure of the salts to confer a patentable distinction to the actual transformed maize plant produced by the process, Ishida et al also anticipate claim 92. See *Best* and *Thorpe* cited above.

Claims 92 and 95 are rejected under 35 U.S.C. 102(b) as being anticipated by Gould et al (1991) submitted by Applicant.

Gould et al teach *Agrobacterium*-mediated transformed maize plants of the hybrid variety Funk's G90 (see, e.g., page 426, Abstract). These maize plants are indistinguishable from those claimed, despite the alternate method of making them. See *Best* and *Thorpe* cited above.

Claims 90, 92-93 and 95-96 are rejected under 35 U.S.C. 102(b) as being anticipated by each of Schlappi et al, Grimsley et al (1988), and Ritchie et al, all submitted by Applicant.

The claims are broadly drawn to *Agrobacterium*-transformed maize cells and maize plants, wherein said maize plants may include non-A188 inbred maize plants (claims 90, 93 and 96), wherein immature embryos are cultured with *Agrobacterium* to produce the resultant plants, wherein the embryos are cultured on a medium comprising

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mineral salts which may exclude MS salts (claim 95) and which may include N6 salts (claim 92), and wherein the transformed maize plants are capable of selection.

Schappi et al teach *Agrobacterium*-mediated transformation of maize plants, wherein immature embryos of the non-A188 inbreds bx/bx, W23 and 880254A were cultured on MS salts, wherein plantlets were obtained from cells of the transformed embryos, and wherein the plantlets were selected by the presence of viral symptoms conferred by viral DNA also present in the transformation vectors (see, e.g., pages 8-9 and 14-15).

Grimsley et al (1988) teach *Agrobacterium*-mediated transformation of the non-A188 inbreds GB and B73 via injection of the shoot meristem, wherein transformed cells and plants can be selected by the presence of viral symptoms (see, e.g., pages 186-187).

Ritchie et al teach the *Agrobacterium*-mediated transformation of the non-A188 inbreds Oh43 and B73 via inoculation of seedlings derived from immature embryos, wherein the transformed maize cells and seedlings were selected by their expression of beta-glucuronidase which conferred blue pigmentation, wherein the transformation vectors also comprised selectable kanamycin resistance genes (see, e.g., pages 253, 255, 259 and 263).

Any differences between the claimed methods of making the *Agrobacterium*-transformed maize plants and those taught by the prior art would not confer patentable distinction to the resultant transformed maize products, as discussed above. See *Best* and *Thorpe* cited above.



Claims 90-93 and 95-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of Schlappi et al, Grimsley et al (1988), and Ritchie et al, all submitted by Applicant.

Claim 91 is drawn to transformed seeds of an Agrobacterium-transformed maize inbred other than A188.

The teachings of the prior art have been summarized above. The prior art does not explicitly teach transformed seeds produced by Agrobacterium-transformed maize plants.

Furthermore, each reference suggests the use of their techniques and known selectable marker genes for the production of stably transformed maize plants (see, e.g., Schlappi et al, page 14, column 1, penultimate paragraph; Grimsley et al, page 186, column 1, bottom paragraph; Ritchie et al, page 263, column 2, last full paragraph).

It would have been obvious to one of ordinary skill in the art to utilize the Agrobacterium-mediated maize transformation techniques taught by each of the cited references, and to modify those techniques by growing the plant to maturity to produce seed, given the recognition by those of ordinary skill in the art of the advantages of seed propagation of valuable genotypes. It would have also been obvious to utilize known selection markers such as selectable antibiotic resistance markers (including the kanamycin resistance marker taught by Ritchie et al), for the production of stably transformed maize plants, given the recognition by those of ordinary skill in the art of the value of stably transformed whole plants for agronomic or industrial purposes as well as for the propagation of desirable genotypes, and as suggested by each reference.

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Claims 94 and 97 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest the successful *Agrobacterium*-mediated transformation of the particularly claimed maize non-A188 inbreds.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (571) 272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (571) 272-0804. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

April 2, 2004

DAVID T. FOX  
PRIMARY EXAMINER  
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